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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/783,749 | 02/19/2004 | Yeung Siu Yu | LSI0108/US/2 | 7382 |
| 33072 7590 02/09/2007 KAGAN BINDER, PLLC SUITE 200, MAPLE ISLAND BUILDING 221 MAIN STREET NORTH STILLWATER, MN 55082 | | | EXAMINER GITOMER, RALPH J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1657 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 02/09/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/783,749

Applicant(s)

SIU YU, YEUNG

Examiner

Ralph Gitomer

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The amendment, RCE request and IDS received 1/3/07 have been entered and claims 17-22 are presently pending in this application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Yum, Wang, Rapkin and Kronish.

Yum (6,251,083) entitled "Interstitial Fluid Methods and Devices for Determination of an Analyte in the Body" teaches in column 7 lines 50-59, reaction zones are isolated from other reaction zones by a hydrophobic barrier such as hot melt adhesive or a silicone and fluorocarbon coating.

Wang (4,687,529) entitled "Method of Making a Reagent Test Device Containing Hydrophobic Barriers" teaches in column 3, a test device with a hydrophobic barrier layer to which a plurality of spaced apart reagent matrices are affixed. This approach virtually eliminates cross contamination between adjacent reagent areas of multiple reagent test devices but requires an extra step of applying hydrophobic material to the device. In another patent, there is a test device for more than one sample components, each area being separated by a nonabsorbent barrier portion. In column 5 lines 34-38, a device with alternating reagent pads and barrier pads attached to a substrate is described. See claim 1.

Rapkin (4,301,115) entitled "Test Device Resistant to Cross Contamination Between Reactant Areas and Process for Making It" teaches in column 3 last paragraph bridging to column 4, reagent test strip having spaced reagent impregnated test areas for more than one sample component separated by a barrier portion that is hydrophobic. And N-Multistix is described as having hydrophobic interstices between adjacent matrices. In column 9 first full paragraph, a hydrophobic layer is applied by means known in the printing art. See claim 13.

Kronish (3,645,853) entitled "Diagnostic Composition and Method for the Detection of Nitrate Reduction" teaches in column 2 lines 47-61, a barrier separates the reagent regions on the test strip. See claim 1.

All the features of the claims are taught by each of the above references for the same function as claimed. Regarding claim 18 directed to hydrophobic ink, the hydrophobic compositions shown in the above references could be applied or employed as ink.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the preamble is directed to determining the concentration of at least one analyte but the last step is directed to an amount of the analyte.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yu (6,723,500) is the parent patent.

Karinka (6,939,450) teaches in column 2 second full paragraph printing a hydrophobic layer. See also column 3 second full paragraph.

Goerlach-Graw (5,556,789) teaches hydrophobic barriers to change analyte paths.

Nelson (US 2004/0152207 A1) entitled "Enzyme Substrate Delivery and Product Registration in One Step Enzyme Immunoassays" teaches in paragraph 10, a sample pad with two lanes separated by a hydrophobic barrier where each lane contains different reagents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1657

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ralph Gitomer
Primary Examiner
Art Unit 1657